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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,298	06/20/2003	Julian N. Nikolchev	016355-002580US	6671

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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,298

Applicant(s)

NIKOLCHEV ET AL.

Examiner

Kathryn Odland

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/6/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the preliminary amendment dated March 17, 2004. Claims 12-81 are under consideration.

Response to Remarks/Arguments

In regard to applicant's comments requesting interference procedures, given the application in which the claims have been copied has been withdrawn from issue, there is no longer a basis to institute an interference procedure between the subject applications. Should common allowable subject matter be found in the subject applications, reconsideration will be given for instituting interference procedures.

Further, the support for the subject matter of the copied claims lies in the instant application. Applicant's request for interference requires support from previously filed parent applications such as US Patent No. 6,176,240 which do not support the copied in the same manner as the instant application.

Information Disclosure Statement

The non-patent literature documents for the IDS filed August 29, 2003 are missing from the application. Thus, the IDS has not been considered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3743

2. Claims 12-14, 19-21, 26, 35-39, 48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk in US Patent No. 5,163,958

Regarding claims 12, 13, 19, 20, 35, 36, 37, 38, and 39, Pinchuk discloses a device capable of functioning as a contraceptive or sterilization device for occluding a reproductive body lumen to prevent the passage of reproductive cells. Applicant is reminded that intended use does not hold patentable weight in apparatus claims. Further, the device is capable of performing the intended use and most stent devices state their ability to be used in fallopian tubes. Moreover, column 1, lines 25-30 discusses that stents are often used in aneurysm conditions, thus, forming occlusions. There are a plethora of patents where stent-like devices used in the vascular system can be also use/adapted for use in the fallopian tubes. The device of Pinchuk also has a tubular member (21, 41) having a first end, a second end, and a lumen extending therein (as seen in the figures), which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration, as recited throughout the specification and seen in the figures. The device also has a mesh/occlusion member (27 and 26a, etc.) connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen, as recited in column 4, with emphasis on lines 4-10, 26-28 and 30-40.

Regarding claims 14, 21, Pinchuk discloses a catheter (such as 53) and a device capable of functioning as a contraceptive device (21, 41). Applicant is

reminded that intended use does not hold patentable weight in apparatus claims. Further, the device is capable of performing the intended use and most stent devices state their ability to be used in fallopian tubes. Moreover, column 1, lines 25-30 discusses that stents are often used in aneurysm conditions, thus, forming occlusions. There are a plethora of patents where stent-like devices used in the vascular system can be also use/adapted for use in the fallopian tubes. The device of Pinchuk also has a tubular member (21, 41) having a first end, a second end, and a lumen extending therein (as seen in the figures), which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration, as recited throughout the specification and seen in the figures. The device also has a mesh/occlusion member (27 and 26a, etc.) connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen, as recited in column 4, with emphasis on lines 4-10, 26-28 and 30-40.

Regarding claim 26, Pinchuk discloses that as discussed above as well as a second tubular configuration that has a larger transverse dimension than the first tubular configuration, as seen if the figures.

Regarding claim 48, Pinchuk discloses that as applied to claim 38 as well as a tubular body (such as 21, 41, etc.) configured for sufficient time for tissue

growth to epithelialize at least an expanded portion of the tubular body, as recited in column 4.

Regarding claim 50, Pinchuk discloses that as applied to claim 38, as well as a device that is capable of having at least part of the tubular body have an outer transverse dimension in the expanded configured configuration that substantially conform to the inner transverse dimensions of the lumen at the expansion site, as seen in the figures. This would correspond to the intended application.

3. Claims 22-25, 27-34, 40-47, 49, 51-53, 66-71, 73-79 and 81 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pinchuk in US Patent No. 5,163,958.

Regarding claims 22, 25, 27, 34, 40, 47, 52, 66-71, 74 and 81, Pinchuk discloses a device capable of functioning as a contraceptive device, as discussed above. Pinchuk also discloses a tubular body (such as 21, 41, etc.) that is expandable from a first tubular configuration to a second larger tubular configuration, as recited throughout the specification, with emphasis on column 5, lines 45-60 and column 6. The second configuration is larger in diameter. The second configuration facilitates securing at least a portion to a wall of the lumen. The device has an open framework and facilitates ingrowth of tissue, as recited in column 4 and seen in the figures. The device also has a member (such as

Art Unit: 3743

26a, 27, etc.) that is configured to support tissue growth, as recited in column 4.

Given the coating process there will necessarily be some of the coating that is contained within the tubular body. Nonetheless, it would be obvious if not inherent to also have the coating within for the purpose of further promoting ingrowth. Moreover, applicant discloses numerous embodiments and does not demonstrate the criticality for the member to be within. Thus, all embodiments can be considered equivalents.

Regarding claim 23, Pinchuk discloses that as applied to claim 22 as well as a member (such as 26a, 27, etc) that provokes an inflammatory response, as discussed in column 4.

Regarding claim 24, see that discussed above. The device of Pinchuk also has an open framework, as seen in figure 1, for example.

Regarding claims 28-33, and 41-46, applicant recites different embodiments of the tubular member. They are considered equivalents since the current application does not demonstrate the criticality for any particular tubular structure. Thus, the structure of Pinchuk demonstrates a helical wire and meets the claim limitation.

Regarding claim 49, Pinchuk discloses that as applied to claim 408 as well as a tubular body (such as 21, 41, etc.) configured for sufficient time for tissue growth to epithelialize at least an expanded portion of the tubular body, as recited in column 4.

Regarding claims 51 and 53, Pinchuk discloses that as applied to claims 40 and 47, as well as a device that is capable of having at least part of the tubular body have an outer transverse dimension in the expanded configured configuration that substantially conform to the inner transverse dimensions of the lumen at the expansion site, as seen in the figures. This would correspond to the intended application.

Regarding claims 73-79, Pinchuk discloses that as applied to claim 66. Further, the device is capable of contributing to an occlusion of the reproductive lumen. Applicant is reminded that intended use does not hold patentable weight in apparatus claims. The device is capable of performing the function and it is well known in the art to place stent-like structures in the fallopian tubes.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3743

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15-18, 54-65, 72 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lan in CN 1073088 in view of Pinchuk in US Patent No. 5,163,958.

Regarding claim 15, Lan discloses a method of contraception via inserting within a desired body lumen a contraceptive device comprising a tubular member and a mesh member connected thereto. Pinchuk discloses an expandable tubular structure with mesh as discussed above. Therefore, it would be obvious if not inherent to expand the tubular member within the body lumen and securing the expanded tubular member to a wall portion defining at least in part as well as epithelializing the mesh member to occlude the body lumen. Thus, it would be obvious if not inherent to assure the system of method of Lan use the expandable structure as taught by Pinchuk for the purpose of proper ingrowth.

Regarding claims 16 and 17, Lan as modified by Pinchuk disclose that as applied to claim 15 and the modification would further yield expanding the tubular member by releasing a radially compressive force on the tubular member, as taught by Pinchuk in column 6. Pinchuk also teaches a catheter (such as 53)

Regarding claim 18, Lan as modified by Pinchuk disclose that as applied to claim 15 and the modification would further yield an expanded tubular member that is disposed within the body lumen for sufficient time for it to be epithelialized within the body lumen and thereby secured to the wall portion.

Regarding claims 54-65 and 80, applicant is directed above to the corresponding subject matter as previously discussed.

Regarding claim 72, Lan discloses a method of contraception. Pinchuk teaches an expandable device capable of occlusions. Thus, it would be obvious when employing the device of Pinchuk for contraception to use a contraceptive agent, as obvious if not inherent.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 12-81 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,684,884.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter.

Art Unit: 3743

8. Claims 12-81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 10/641,333. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claim 72 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/779,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows:

US Patent No. 5,507,768

US Patent No. 5,222,964

US Patent No. 5,197,978

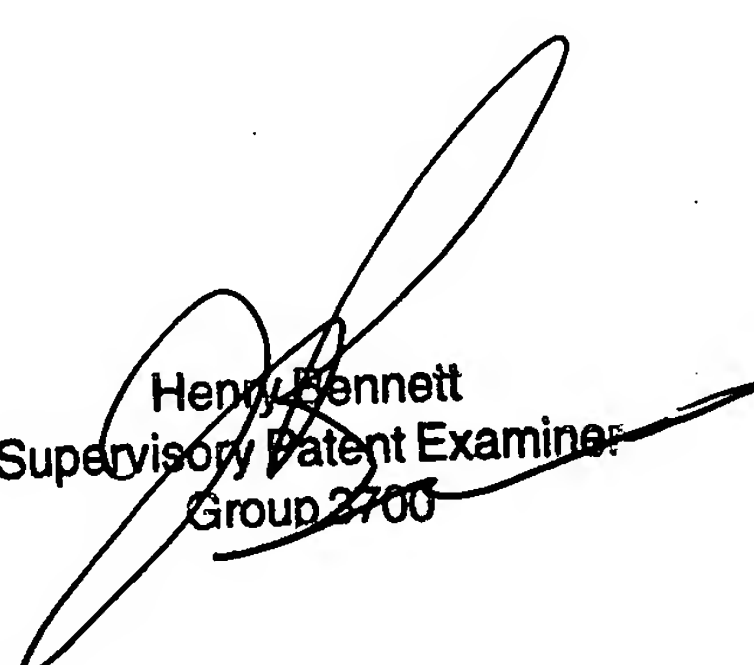
These show stent-like structures in the fallopian tubes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (571) 272-4801. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



Henry Bennett
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